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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER

ART UNIT	PAPER NUMBER
	14

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/365,576	Moore et al.
Examiner	**Art Unit**
Michael Pak	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Apr 13, 2001* .

2a) [ ] This action is **FINAL**. 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *1-27* is/are pending in the application.

4a) Of the above, claim(s) *1-6, 8-9, 11-12, 17-26* is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *7, 10, 13-16, and 27* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____ .
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) [X] Notice of References Cited (PTO-892)
16) [X] Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s). *5, 10*
18) [ ] Interview Summary (PTO-413) Paper No(s). _____
19) [ ] Notice of Informal Patent Application (PTO-152)
20) [ ] Other:

DETAILED ACTION

Response to Election

1. Applicant's election without traverse of Group IV, claims 7, 10, 13-16 and 27 in Paper No. 13 is acknowledged.

Claim Objections

2. Claims 15-16 and 27 are objected to because of the following informalities. Appropriate correction is required.

Claim 15 uses the acronym β-PARE which should be identified with the full name.

Claim 16 uses the acronym EcPE which should be identified with the full name.

Claim 27 is dependent on a non-elected claim.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 7, 10, 13-16 and 27 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

The claims are directed to a polypeptide of PIP or comprising substantially identical sequence of SEQ ID NO:3 where

the EIP is an orphan receptor with no known ligand. The state of the art at the filing date of the invention was such that the closest protein by percent identity was also an orphan receptor (Liao et al., US 5,639,616). The specification as filed does not disclose or provide evidence that points to a property of the claimed receptor such that another non-asserted utility would be well established. Since the function of the protein is not known because the ligand is not known, the protein lacks well established utility. The specification on page 40 disclose the asserted utility of using the receptor to facilitate the production of pharmacologic modifiers of EXR function. However, there is no nexus between the unknown properties of the receptor polypeptide and the treatment of any diseases. Thus, the claimed invention lacks substantial utility because further research to identify or reasonably confirm a "real world" context of use is required. Any utility of the nucleic acid encoding the protein or other specific asserted utility is directly dependent on the function of the protein. A circular assertion of utility is created where the utility of the protein is needed to break out the circular assertion or utility. The orphan receptor polypeptide does not have a well established utility because different receptors would have different functions and the skilled artisan would have to determine the function of the orphan receptor. The claimed polypeptides do not have

substantial utility because the skilled artisan would need to prepare, isolate, and analyze the protein in order to determine its function and use. Therefore, the invention is not in readily available form. Instead, further experimentation of the protein itself would be required before it could be used.

Claims 7, 10, 13-16 and 27 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 7, 10, 13-15, and 27, are rejected under 35 U.S.C. 102(b) as being anticipated by Leid et al.(Cell, 1992).

Leid et al. disclose human retinoic acid receptors(RAR) and thyroid receptors which bind to RXR to form heterodimers(page 377, abstract; page 376, left column, middle paragraph). The heterodimer of RAR and RXR binds βRARE (page 383, right column, second paragraph). The cDNA encoding human RAR is used for expression of recombinant proteins (page 390, right column, bottom section; page 391, left column, top two sections).

Claims 7 and 10 encompass human RAR because the recitation of "substantially identical" is defined in the specification (page 6, lines 27-34) to encompass unlimited number of non-conservative substitutions, deletions, and insertions and as defined RAR is substantially identical to SEQ ID NO 3.

7. Claims 7, 10, 13-14, 16, and 27, are rejected under 35 U.S.C. 102(b) as being anticipated by Thomas et al.(Nature, 1993).

Thomas et al. disclose the ecdysone receptor(EcR) expressed in HeLa cells which binds to RXR to form a heterodimer(page 471, abstract; page 471, right column, first paragraph; page 472, fig.1; page 474, left column, top paragraph). The heterodimer of EcR and RXR binds EcRE (page 471, abstract; page 471, right column, first paragraph; page 472, fig.1). The cDNA encoding EcR is used for expression of recombinant proteins in HeLa cells (page 471, abstract; page 471, right column, first paragraph;

page 472, fig.1).

Claims 7 and 10 encompass EcR because the recitation of "substantially identical" is defined in the specification (page 6, lines 27-34) to encompass unlimited number of non-conservative substitutions, deletions, and insertions and as defined EcR is substantially identical to SEQ ID NO:3. Claims 13-14 and 16 recite "derived from a mammal" and since the specification does not define the term "derived from", the EcR expressed in HeLa cells is interpreted to mean a polypeptide produced or derived from a mammalian cell. HeLa cells are human cell lines.

8. Claims 7, 10, 13-16, and 27, are rejected under 35 U.S.C. 102(e) as being anticipated by Liao et al.(US 5,639,616).

Liao et al. disclose ubiquitous nuclear receptor which is 97.1% identical to SEQ ID NO:3.

Claims 7 and 10 encompass human RAR because the recitation of "substantially identical" is defined in the specification (page 6, lines 27-34) to encompass unlimited number of non-conservative substitutions, deletions, and insertions and as defined RAR is substantially identical to SEQ ID NO 3. The ubiquitous receptor has the identical amino acid sequence as the DNA binding region of SEQ ID NO:5 and thus inherently binds the DNA response element of RARE and ECRE.

9. The prior art made of record and not relied upon is

considered pertinent to applicant's disclosure.

Hogness et al.(US 5514578) is a cumulative reference with Thomas et al.

10. No claims are allowed. SEQ ID NO: 3 is free of the prior art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 5:50 AM to 2:20 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
20 June 2001